CLINICAL TRIALS – REGULATORY START-UP: ANCILLARY APPLICATIONS

Revised April 16, 2025

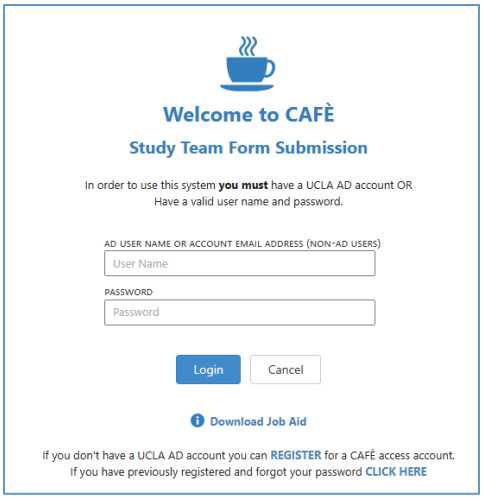
OVERVIEW: APPLYING TO ANCILLARIES

- **Description:** Ancillary services are additional departments that provide support with the protocol procedures which are required to activate human research studies.
    - To determine study's needs, review the sponsor-provided protocol (specifically refer to the schedule of events and manuals).
- **Research Ancillaries Available at UCLA:**
    - Study teams should submit independent applications to each ancillary depending on the protocol's requirements.
        - Submit applications through Café for the following ancillaries:
            - Anesthesiology
            - Cellular Therapy (Bowyer, Stem Cell, Hemapheresis)
            - CPRS/Pathology
            - CTRC
            - DSMB/ISPRC
            - Nuclear Medicine
            - Ophthalmology
        - Submit applications through SafetyNet for the following ancillaries:
            - IBC (Institutional Biosafety Committee)
            - MRSC (Medical Radiation Safety Committee)
        - Radiology Research Imaging
    - Submissions to **Investigational Drug Services (IDS)/Pharmacy** are automatically done when submitting to the IRB.
- **When to initiate ancillary applications:**
    - You can initiate ancillary applications once you:
        - Obtain: IRB# for the study
        - Finalized study manuals
        - Have a final protocol.

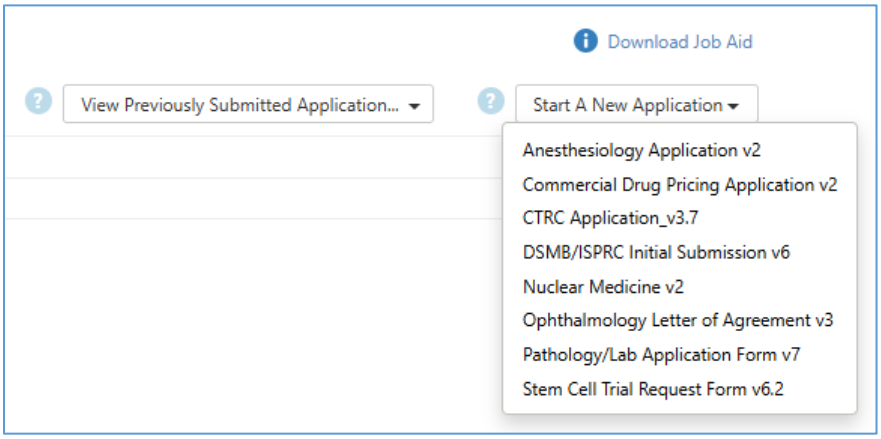
      You will need to reference these for each submission.
- **Timeline:**
    - Approvals/waivers are typically granted **within 7-14 business days of submission**. If you do not receive approval in this timeframe, please follow up with the appropriate ancillary group.
    - You will receive a notification via email that an ancillary approval (quote) has been uploaded into OnCore.
        - Clinical Research Finance (CRF) – formerly known as Coverage Analysis – will build an initial draft budget out for negotiation using the quotes that have been uploaded in OnCore by all ancillaries.

ACTION ITEMS

1. Log into the portal for the applicable ancillary you'd like to apply to.
    a. Access Café and login:

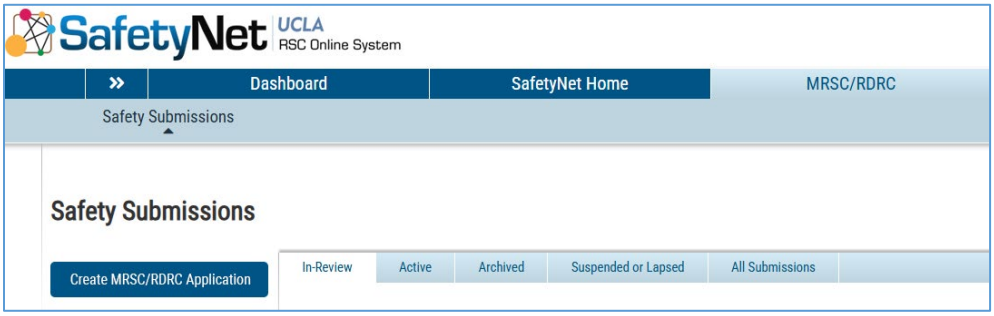


i. Navigate to the top right corner where it says, "Start a New Application" and click the ancillary application you'd like to complete.

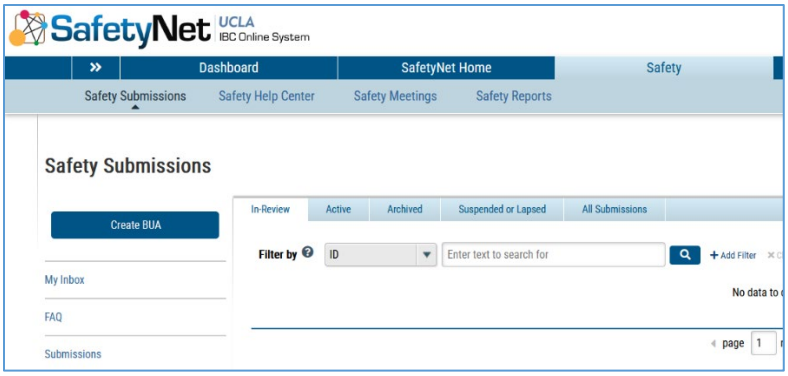


b. Access SafetyNet and login:

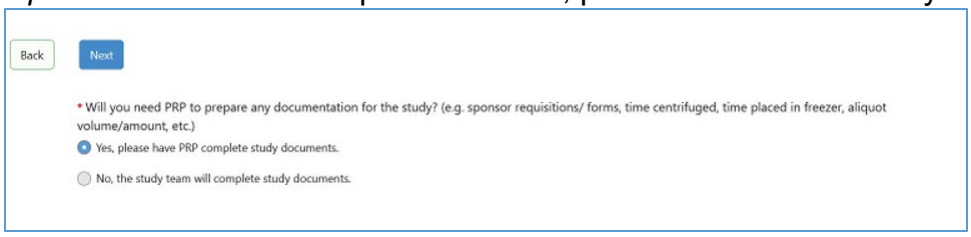
i. For MRSC, navigate to the left corner to create an application:



ii. For IBC, navigate to the left corner to create an application:



2. **How do you know which ancillaries to submit to?**
   - **Anesthesia**
     - Submit application if there are any procedure(s) that require anesthesia within the trial which are specifically required for the study (i.e. not standard of care)
     - *Tip*: use the study biopsy manual to help you complete the application
   - **Cellular Therapy Research Services**
     - Cellular Therapy Research Services is comprised of three departments: Hemapheresis, Bowyer Infusions Center, and Stem Cell Lab.
   - **Center for Pathology Research Services (CPRS)**
     - Central labs for processing
       - Review protocol to determine which lab processing procedures will be needed; Examples of procedures requiring CPRS services: Aliquot processing, biopsies, centrifuging, etc.
       - *Tip #1:* When asked about the start/stop dates, estimate the dates based on protocols schedule of activities.
       - *Tip #2:* When asked the question below, please confirm with study team.



       - When asked to specify authorized pick-up staff in the CPRS application, please list the correct contact information for those who will be picking up samples.
     - If your study does not need CPRS services, you will need to reach out to CPRS and request a waiver for their services.
       - OnCore will place a hold on your study in OnCore without a waiver or approval from CPRS, which will affect a delay in the Budget Out release. Therefore, email CPRS@mednet.ucla.edu and request a waiver be uploaded into OnCore so the study budget build may proceed forward.
   - **Clinical & Translation Research Center (CTRC)**
     - CTRC offers the following:
       - Staffing support for any research clinical procedures/services (e.g. study nurses, medical assistants, vitals, infusions, ECG, etc.)
       - Examination rooms for patient visits
   - **ISPRC/DSMB** *(JCCC Oncology Trials only)*
     - Refers to Internal Scientific Peer Review Committee (ISPRC)/Data Safety Monitoring Board (DSMB)
     - These submissions are required for all oncology trials only.

- **Nuclear Medicine**
  - Nuclear Medicine clinical trials use small amounts of radioactive tracer or drugs that are involved in the study. The radioactive tracer or drug is attracted to specific organs, bones, tissues or cells.
- **Ophthalmology**
  - Supports the ophthalmologic requirements in a clinical trial
  - *Tip*: Confirm if ocular imaging is needed with sponsor prior to completing application.
- **Radiology + Imaging Services**
  - Applicable if imaging (CT, MRI, ultrasound, guided biopsy, etc.) is required per study requirements.
    - *Tip*: Review which anatomical location for which imaging is required and confirm if contrast is needed.
- **Medical Radiation Safety Committee (MRSC)**
  - Why do we apply to MRSC?
    - You must submit an application to the MRSC if the study involves scans/imaging *that involve radiation* (CT, PET, etc.), which may include standard of care (SOC), or beyond standard of care (BSOC).
  - Approval is typically granted within 5 business days.
  - The initial application must be submitted by the PI. However, for future submissions (amendment changes), the PI proxy may complete the submission.
  - Directions to create an application can be found here.
- **Institutional Biosafety Committee (IBC)**
  - The IBC is responsible for establishing, monitoring, and enforcing policies and procedures involving hazardous biological materials and recombinant/synthetic nucleic acids to meet applicable federal, state, local, and institutional regulations and guidelines.
  - The UCLA Institutional Biosafety Committee (IBC) was established as the local review body responsible for oversight of all research activities involving the use of hazardous biological material and recombinant or synthetic nucleic acids

Contact & Resources

- Anesthesia
- Cellular Therapy
- CPRS
- CTRC
  - Handbook
- DSMB/ISPRC
- Nuclear Medicine
- Ophthalmology
- IBC
- Investigational Drug Services
- Radiology
  - MRSC
- UCLA DOM CTP